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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Certifier	J. W. Wadsworth

**Food and Drug Administration**

**21 CFR Part 522**

**Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Hoechst Roussel Vet. The supplemental NADA's provide for use of two additional trenbolone acetate and estradiol ear implants, one for heifers fed in confinement for slaughter for increased rate of weight gain, and the other for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217.

**SUPPLEMENTARY INFORMATION:** Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010, filed supplemental NADA 140-897 that provides for Revalor®-IS ear implants containing 80 milligrams (mg) trenbolone acetate (TBA) and 16 mg estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Hoechst Roussel Vet also filed supplemental NADA 140-992 that provides for Revalor®-IH ear implants containing 80 mg TBA and 8 mg estradiol for heifers fed in confinement for slaughter for increased rate of weight gain.

The supplemental NADA's are approved as of June 19, 2000, and the regulations are amended in 21 CFR 522.2477 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning June 19, 2000, because the applications contain substantial evidence of the effectiveness of the drugs involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the applications and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the implants approved in these supplemental NADA's.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 522**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 522.2477 is amended by revising the first sentence in paragraph (b), by adding paragraph (d)(1)(i)(D), and by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

**§ 522.2477      Trenbolone acetate and estradiol.**

\*      \*      \*      \*      \*

(b) See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii), (d)(2)(iii), and (d)(3) of this section. \* \* \*

\*      \*      \*      \*      \*

(d) \* \* \*

(1) \* \* \*

(i) \* \* \*

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets), or 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(2) \* \* \*

(i) ~~\*\*\*~~ Amount

(A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B) of this section.

(B) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

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(ii) ~~\*\*\*~~ *Indications for use.*

(A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

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Dated: July 18, 2000  
July 18, 2000

Claire M. Lathers

Claire M. Lathers  
Director  
Office of New Animal Drug  
Evaluation  
Center for Veterinary  
Medicine  
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